

TRANSLATION**PATENT COOPERATION TREATY****PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-015	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/013812	International filing date (day/month/year) 22.09.2004	Priority date (day/month/year) 26.09.2003
International Patent Classification (IPC) or national classification and IPC . C12N1/20, A23L1/105, A23L1/20, A61K35/74, A61K35/80, A61K35/78, A61P37/04		
Applicant SOMA, Gen-Ichiro		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>6</u> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-6, 8, 10-34 as originally filed/furnished
- pages* 7, 9, 9/1 received by this Authority on 01.04.2005
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 2-17 as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1, 18-29 received by this Authority on 01.04.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets fig. 1 as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	7, 10-17, 20-24, 26-29	YES
	Claims	1-6, 8, 9, 18, 19, 25	NO
Inventive step (IS)	Claims	10-17, 20-23, 26-29	YES
	Claims	1-9, 18, 19, 24, 25	NO
Industrial applicability (IA)	Claims	1-29	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
Document 1:	JP 06-078756 A (Chiba Flour Mill Co., Ltd.), 22 March 1994 & EP 472467 A & US 5281583 A & JP 06-040937 A & JP 06-090745 A & US 5346891 A & US 5494819 A & JP 04-099481 A		
Document 2:	Hiroyuki INAGAWA et al., "Anti-tumor effect of lipopolysaccharide by intradermal administration as a novel drug delivery system," <i>Aniticancer Research</i> (1997), Vol. 17, No. 3C, pages 2153 to 2158		
Document 3:	Hiroyuki INAGAWA, Gen'ichiro SOMA et al., " <i>Pantoea agglomerans</i> LPS (LPSP) no Naihi Toyo to Lipid A Yudotai ONO-4007 no Keiko Toyo ni yoru IgE Izongata Allergy Hanno no Yokusei Koka," <i>Biotherapy</i> (Tokyo), 1997, Vol. 11, No. 3, pages 464 to 466		
Document 4:	Takashi NISHIZAWA, Gen'ichiro SOMA et al., "Komugi yori Bunri shita <i>Pantoea agglomerans</i> no Seisei Lipopolysaccharide no Seibutsu Kassei ni Tsuite no Kento," <i>Biotherapy</i> (Tokyo), 1992, Vol. 6, No. 3, pages 356 to 357		
Document 5:	Hiroyuki INAGAWA, Gen'ichiro SOMA et al., "Komugi Oyobi Shoshu Gram Insei Kin Yurai		

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Lipo Tato no Keiko Toyo ni yoru Mouse wo
Mochiita Chintsu Koka no Hikaku Kento,"
Biotherapy (Tokyo), 1992, Vol. 6, No. 3,
pages 358 to 359

Document 6: Gen'ichiro SOMA, "Dynamic aspects of cytokine
network to induce antitumor effects by
intradermal administration of low molecular
weight lipopolysaccharides derived from
Pantoea Agglomerans," Advances in
Pharmaceutical Sciences (2000), Vol. 16,
pages 7 to 22

Claims 1 to 6, 8, 9, 18, 19 and 25

The inventions set forth in claims 1 to 6, 8, 9,
18, 19 and 25 lack novelty in the light of document 1.

Document 1 describes an experiment wherein a wheat
flour solution, which was obtained by adding distilled
water to wheat flour, was cultured in a water bath at a
temperature of 37°C while being shaken; 0.5 ml samples of
the solution were collected when the culturing process
had progressed for 0 hours, 1 hour, 2 hours, 3 hours, 4
hours, 6 hours, 8 hours, 10 hours, 12 hours, 20 hours, 24
hours, and 45 hours; the concentrations of the respective
solutions were diluted by a factor of 10^0 to 10^5 ; and
then 100 μ l portions of the diluted solutions were added
to a standard agar culture media, whereafter the number
of living organisms was measured and the colonies of said
living organisms were observed (paragraph [0022]).
Therein, document 1 indicates that it was possible to
obtain bacteria belonging to the genus *Pantoea*, the genus
Serratia and the genus *Enterobacter* from the colonies
that were confirmed after the 8th hour and the 10th hour

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of the culturing process.

In the written response, the applicant asserts that fermentation does not ordinarily occur within a wheat flour solution that is obtained by adding water to wheat flour. However, even though the disclosure "cultured while being shaken" in document 1 does not precisely correspond to fermentation, document 1 specifically indicates that colonies emerged in cases when the wheat flour solution, which was "cultured while being shaken," was diluted and then added to a culture medium (therein, the solution is diluted by a factor of 10^0 to 10^5 , the scope of which includes configurations in which the samples are undiluted), and thus document 1 can be considered to disclose a feature wherein microorganisms of the genus *Pantoea* or the like are cultured in a standard agar culture medium to which wheat flour has been added, even if relatively few microorganisms are actually cultured.

Herein, claim 1 sets forth inventions pertaining to a "fermentation and culturing method wherein a material derived from an edible plant, which includes a sugar that contains a polysaccharide as the primary constituent, is fermented by means of facultative anaerobic gram-negative bacteria that is entirely symbiotic with a plant." Therein, the scope of the abovementioned disclosure includes culturing by means of culture media that include a component other than wheat flour as the "material derived from an edible plant, which includes a sugar that contains a polysaccharide as the primary constituent," and thus the inventions that are set forth in the abovementioned claims of the present application cannot be differentiated from the invention that is disclosed in

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document 1.

Claims 7 and 24

The inventions set forth in claims 7 and 24 do not involve an inventive step in the light of document 1.

Prior to the priority date of the present application, microorganisms of the species *Pantoea agglomerans*, which can be isolated from wheat, were well-known as one species belonging to the genus *Pantoea* (if necessary, refer to documents 2 to 6), and thus it would have been possible to employ microorganisms of the species *Pantoea agglomerans* as the microorganisms that belong to the genus *Pantoea*, as appropriate.

Claims 10 to 17, 20 to 23 and 26 to 29

The inventions pertaining to a "method for fermenting and culturing a material that is derived from seaweed" and a "fermented plant extract that is obtained by fermenting wheat flour, soybean curd lees or marine algae by means of microorganisms of the species *Pantoea agglomerans*," which are set forth in claims 10 to 17, are not disclosed in documents 1 to 6, and it would not have been possible to invent the inventions in question by simply combining the features that are disclosed in the documents in question.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 to 29 set forth inventions pertaining to a "fermentation and culturing method for culturing the facultative anaerobic gram-negative bacteria" that is entirely symbiotic with a plant while simultaneously fermenting a "material derived from an edible plant, which includes a sugar that contains a polysaccharide as the primary constituent," by means of said "facultative anaerobic gram-negative bacteria that is entirely symbiotic with a plant." With regards to the abovementioned fermentation and cultivation, however, the description only specifically indicates that the "emergence of colonies was observed after culturing for 6 days at a temperature of 37°C in a M9 agar culture medium that includes 0.5% wheat flour as a carbon source;" that "water was added to the wheat flour in order to form a wheat flour suspension and then the supernatant liquid therefrom was added to an L-broth agar culture medium for cultivation overnight at a temperature of 37°C;" that "refined water was added to the wheat flour, the product was autoclaved and then an α -amylase was added thereto, whereafter the resulting product was fermented in a wheat flour culture medium that includes a calcium chloride solution, a magnesium chloride solution, a mixed solution comprising an inorganic salt, and a solution (the wheat flour amylase processing solution) that had been heated in a water bath with a temperature of 65°C for 4 to 12 hours, said components being included in the amounts that are presented in table (1);" that "fermentation was carried out by means of microorganisms belonging to the species *Pantoea agglomerans* in a bean curd lees-based culture

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medium that is obtained by adding a primary potassium phosphate, a secondary sodium phosphate, an edible salt and potassium chloride to bean curd lees;" that "fermentation was carried out by means of microorganisms belonging to the species *Pantoea agglomerans* in a rice flour-based culture medium that is obtained by adding a primary potassium phosphate, a secondary sodium phosphate, an edible salt and potassium chloride to rice flour," and that "fermentation was carried out by means of microorganisms belonging to the species *Pantoea agglomerans* in a female wakame seaweed-based culture medium that is obtained by adding a primary potassium phosphate, a secondary sodium phosphate, an edible salt and potassium chloride to dried female wakame seaweed."

The scope of the disclosure specifying a "material derived from an edible plant, which includes a sugar that contains a polysaccharide as the primary constituent," and the scope of the disclosure specifying a "facultative anaerobic gram-negative bacteria that is symbiotic with a plant" include a large number of materials or bacteria; therefore, in the light of the abovementioned disclosures in the description there cannot be considered to be sufficient support in the description to demonstrate that it is possible to obtain preparations that exhibit a immunoactivating effect, a humidity retention effect, an allergic reaction reducing effect and the like by means of the inventions that are set forth in the abovementioned claims while using any "material derived from an edible plant, which includes a sugar that contains a polysaccharide as the primary constituent," and any "facultative anaerobic gram-negative bacteria that is symbiotic with a plant."

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